UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, **Plaintiff,** **v.** **FERA PHARMACEUTICALS, LLC, et al.,** **Defendants.**	No. 15–cv–3654 (KM)(MAH) **OPINION** **(Preliminary Injunction and Motion to Dismiss)**

KEVIN MCNULTY, U.S.D.J.:

The plaintiff, Fresenius Kabi USA, LLC, brings two motions against two of the defendants in this suit, Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC (collectively, "Fera")[1]: 1) a motion to dismiss Fera's inequitable conduct counterclaims (ECF No. 89), and 2) a motion for preliminary injunction (ECF NO. 187). Fresenius's underlying suit against Fera is for patent infringement. The patents-in-suit are Patent Nos. 9,006,289 ("the '289 patent"), 9,168,238 ("the '238 patent"), and 9,168,239 ("the '239 patent"). All three describe formulations of levothyroxine, a hormone produced by the thyroid. These patents claim a form of lyophilized (i.e. freeze-dried) levothyroxine that can be reconstituted and injected into patients who lack a properly functioning thyroid. (Pl. Opening 1) Claims 1, 2, 4, 14, 15, and 16 of the '289 patent are the subject of this preliminary injunction motion. (Prel. Inj.

[1] At the parties' request, this patent infringement suit was consolidated for pretrial purposes with one against InnoPharma, Inc. and InnoPharma Licensing, LLC (collectively, "InnoPharma"), originally filed under the docket number 15–3655. (*See* ECF No. 79) Fresenius has not asked for a preliminary injunction against InnoPharma. A third suit, docket number 15–3853, was originally consolidated with these two, but those defendants settled with Fresenius after the opening briefs were filed. (*See* ECF No. 120)

Br. 9)[2] Simultaneously herewith, I am filing a *Markman* opinion, construing the terms of the patent, which is incorporated herein.

The Food and Drug Administration ("FDA") approved Fresenius's New Drug Application ("NDA") on June 24, 2011. (3AC Fera ¶ 15) The '289 patent

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[2] Citations to the record will be abbreviated as follows:

"3AC Fera" — Third Amended Complaint of Fresenius against Fera (ECF No. 83).

"Fera Answer" — Fera's Answer to 3AC Fera (ECF No. 84).

"'084 Application" — U.S. Provisional Patent Application No. 61/529,084, Appendix B to the Fera Answer (ECF No. 84–2).

"'884 application" — non-provisional Patent Application No. 13/597,884, Appendix C to the Fera Answer (ECF No. 84–3).

"Usayapant Decl." — December 23, 2014 Declaration of Dr. Arunya Usayapant, Appendix I to the Fera Answer (ECF No. 84–9).

"Notice of Allowance" — Notice of Allowance of the '884 application by the USPTO, Appendix J to the Fera Answer (ECF No. 84–10)

"Prel. Inj. Br." — Fresenius's Brief in Support of their Motion for Preliminary Injunction (ECF No. 188).

"Pl. Ex." — Fresenius's Exhibits (ECF Nos. 187–2 to 187–9), attached to the Declaration of Keith J. Miller (ECF No. 187–1).

"Meachum Decl." — Declaration of Scott Meachum (ECF No. 188–2).

"Prel. Inj. Opp." — Fera's Brief in Opposition to Fresenius's Motion for Preliminary Injunction (ECF No. 253).

"Def. Ex."— Fera's Exhibits (ECF Nos. 253–2 to 253–16), attached to the Declaration of Adam D. Sussman (ECF No 253–1).

"Prel. Inj. Reply" — Fresenius's Reply Brief in Support of their Motion for Preliminary Injunction (ECF No. 265).

"Bedford"— Description of Bedford Laboratories grandfathered levothyroxine formulation (Ex. D to Def. Ex. 2 (ECF No. 253-4)).

"Nentwich"— Description of grandfathered levothyroxine formulation in Intravenous Therapies textbook by Phyllis Nentwich (Ex. G to Def. Ex. 2 (ECF No. 253-4)).

"'289 Patent" — United States Patent No. 9,006,289, Pl. Ex. 1 (ECF No. 187–2).

"'238 Patent" — United States Patent No. 9,168,238, Pl. Ex. 2 (ECF No. 187–3).

"'239 Patent" — United States Patent No. 9,168,239, Pl. Ex. 3 (ECF No. 187–4).

was issued on April 14, 2015, and is due to expire on October 3, 2032. (3AC Fera ¶¶ 10, 16) The '238 and '239 patents were issued on October 27, 2015, and are due to expire on August 29, 2032. (3AC Fera ¶¶ 11–12, 16) Fera filed an Abbreviated New Drug Application ("ANDA") that sought approval to commercially market a generic version of Fresenius's patented levothyroxine formulations. (Fera Answer ¶ 17) This lawsuit followed.[3]

On July 25, 2016, I convened a hearing on the motion of Fresenius for a preliminary injunction. To shorten the hearing, I directed the parties that I would accept affidavits in lieu of direct testimony, and offered both sides the opportunity to cross-examine. Both sides declined the opportunity, and opted to rely on their papers. As a result, any facts related herein rest on the persuasiveness, or not, of written representations; there was no opportunity to assess credibility. This opinion is structured primarily as a discussion of the motion for a preliminary injunction. The arguments on the motion to dismiss the inequitable conduct claims are discussed in the context of the likelihood of success on the merits.

I. BACKGROUND

A grandfathered version of a levothyroxine injectable, not approved by the FDA, has been available in the United States since 1969. (Prel. Inj. Opp. 4 (citing Def. Ex. 253-6 at 6280)) In the early 2000s, APP Pharmaceuticals marketed that grandfathered version. On December 18, 2006, APP received a warning letter from the United States Food and Drug Administration notifying it that an NDA would be required. (Meachum Decl. ¶ 14) In 2008, Fresenius acquired APP. In 2010, Fresenius filed an NDA on a "more stable formulation of its Levothyroxine product." That NDA was approved on June 24, 2011.

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[3] In many cases, a 30-month stay operates to give the parties and the court breathing space to decide issues of patent validity and infringement. The parties agree that, for various reasons of timing, the 30-month stay does not apply here. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

(Meachum Decl. ¶¶ 15–17; *see also* Prel. Inj. Opp. 4) Based on that new, FDA-approved formulation, Fresenius applied for and eventually received the '289, '238, and '239 patents.

Fresenius's newly patented formulations contain levothyroxine, a buffer, and a specific amount of a bulking agent called mannitol. The innovation at the heart of Fresenius's patents is a claim that a lower amount of mannitol, as compared with the grandfathered versions, unexpectedly increased the stability of the formulation. (Prel. Inj. Br. 5)

Fera and InnoPharma filed Abbreviated New Drug Applications ("ANDA") that sought approval to commercially market generic versions of Fresenius's patented levothyroxine injections. Fresenius, claiming that these would infringe its patents, seeks to enjoin them from doing so.

II. ANALYSIS

Whether a preliminary injunction is warranted depends on four factors: (1) whether the moving party is likely to succeed on the merits; (2) whether the moving party is likely to suffer irreparable harm in the absence of preliminary relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether an injunction is in the public interest. *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20, 129 S. Ct. 365 (2008)); *accord Columbia Gas Transmission, LLC v. 1.01 Acres, More or Less in Penn Twp., York Cnty., Pa., Located on Tax ID # £440002800150000000 Owned by Brown*, 768 F.3d 300, 315 (3d Cir.2014). "These traditional four factors 'apply with equal force to disputes arising under the Patent Act.'" *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391, 126 S. Ct. 1837 (2006)). No individual factor is dispositive. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988) However, "a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction." *Altana*

Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009); *accord Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 475 (D.N.J. 2015).

A. Likelihood of Success on the Merits

Fera's challenge is directed primarily to the first factor: Fresenius's likelihood of success on the merits of its claim of patent infringement.

1. Federal Circuit standard

The United States Court of Appeals for the Federal Circuit, which has appellate jurisdiction over patent cases, applies the law of the regional circuits when reviewing preliminary injunction decisions. *Aevoe Corp. v. AE Tech Co.*, 727 F.3d 1375, 1381 (Fed. Cir. 2013) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1367 (Fed. Cir. 2008)). However, it applies Federal Circuit law to substantive matters of patent infringement, including the first of the four preliminary injunction factors: the likelihood of success in establishing patent infringement. *Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012). And Fed. R. Civ. P. 65, of course, applies regardless.

In *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, the Federal Circuit announced, or reaffirmed, the standard by which district courts hearing patent cases should review the preliminary injunction factor of likelihood of success on the merits: If the alleged infringer "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue." 239 F.3d 1343, 1350–51 (Fed. Cir. 2001) (internal quotation marks omitted) (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). The *Amazon* court further explained that, rather than the "clear and convincing" standard for proving patent invalidity at trial, "[v]ulnerability is the issue at the preliminary injunction stage." *Id.* at 1359.

Amazon's standard may have been cast into doubt, however, by the subsequent Supreme Court case of *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391, 126 S. Ct. 1837 (2006). In *eBay*, the Supreme Court reviewed a

Federal Circuit post-trial decision to apply a "'general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.'" 547 U.S. at 391 (quoting *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005)). The Court reemphasized that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id.* at 394. In short, the Supreme Court seemed to reemphasize the primacy of the traditional four-factor analysis for injunctive relief, albeit in the context of a permanent, not preliminary, injunction. *Id.* at 391.

Doubts have thus arisen as to the continuing viability of the Federal Circuit's holding that, for preliminary injunctive relief, the "substantial question" standard requires only a showing of patent "vulnerability." Thus, in the aftermath of *eBay*, Judge Newman dissented in two Federal Circuit decisions that vacated preliminary injunctions in patent cases. Both times, she objected to the majorities' holdings that a "substantial question" of invalidity suffices to defeat a motion for a preliminary injunction. *Erico*, 516 F.3d at 1359–60; *Andrx Pharm.*, 452 F.3d at 1349–52. The fullest statement of Judge Newman's views is contained in her opinion in *Sandoz, supra.* There, although she wrote for the majority, the relevant section of her opinion was not joined by her companion in the majority or by the dissenting Judge Gajarsa. Judge Newman thoroughly reviewed the preliminary injunction standards of all the other circuits and argued that "all refer to the likelihood of the eventual outcome, not whether a substantial question has been raised." 544 F.3d at 1365. In Judge Newman's view, certain panels of the Federal Circuit had departed from the proper standard when they looked only to the alleged infringer's raising of a "substantial question" as to the patent's validity. That approach, in her view, undermined the proper application of the "likelihood of success on the merits" standard. *Id.* at 1364.

The following year, both Judge Newman and Judge Gajarsa joined an opinion by Judge Plager that attempted to reconcile the "substantial question" standard with the traditional equitable factors. *See Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372 (Fed. Cir. 2009). *Titan Tire* started from the basic principle that "[i]n assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial." *Id.* at 1376 (citing *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429, 126 S. Ct. 1211 (2006)). Issued patents maintain a statutory presumption of validity at trial, and the defense of invalidity must be proven by clear and convincing evidence. *Id.*; *see* 35 U.S.C. § 282. On a motion for preliminary injunction, *Titan Tire* held, the patent likewise enjoys a presumption of validity. Should its validity be challenged, however, the patentee has the burden to respond and show a likelihood of success on the merits. *Id.* at 1377.

The *Titan Tire* court then analyzed *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878 (Fed. Cir. 1992), which was cited in the *Genentech* case from which the *Amazon* panel drew the "substantial question" standard. In *New England Braiding*, the court wrote:

> The district court cannot be held to have erred in deciding that the patentee failed to make a sufficient showing of likelihood of success required to support a preliminary injunction where the evidence presented in support of invalidity *raises a substantial question*, although the defense may not be entirely fleshed out.... While it is not the patentee's burden to prove validity, *the patentee must show that the alleged infringer's defense lacks substantial merit.*

970 F.2d at 883 (emphasis added). Viewing this paragraph as a whole, *Titan Tire* concluded that a trial court should consider both the evidence of invalidity and the patentee's rebuttal evidence. 566 F.3d at 1377–78 (citing *Genentech*, 108 F.3d at 1364 ("In other words, if Novo raises a 'substantial question' concerning validity ... (*i.e.*, asserts a defense that Genentech cannot show 'lacks substantial merit') the preliminary injunction should not issue").

Attempting to synthesize the case law, *Titan Tire* stated that denial of a preliminary injunction entails a conclusion "that the patentee is unlikely to succeed on the merits of the validity issue because the patentee is unable to establish that the alleged infringer's invalidity defense lacks substantial merit." *Id.* at 1378. That is a substantial bar, said *Titan Tire,* but it does not prematurely require that the opponent of relief meet its ultimate burden of proving invalidity by clear and convincing evidence. Rather, at the preliminary injunction stage, the court must "assess the potential of a 'clear and convincing' showing [of invalidity] in the future, but in terms of what is 'more likely than not' presently." *Id.* at 1380.

Judges of the Federal Circuit—albeit in nonprecedential or nonmajority decisions—have questioned whether the *Titan* synthesis has truly reconciled the Federal Circuit preliminary injunction standard with the traditional equitable factors, in keeping with *eBay, supra.* For example, *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, 431 F. App'x 884, 887 (Fed. Cir. 2011), an unpublished decision, continued to cite the "vulnerability" language from *Amazon*, to the evident consternation of Judge Newman: "[T]he attempted reconciliation in *Titan Tire* appears to have failed, for this panel provides no qualification for its position that if validity is reasonably questioned, the injunction will be denied." *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, 660 F.3d 1293, 1299 (Fed. Cir. 2011) (Newman, J., dissenting from denial of rehearing, joined by Judges O'Malley and Reyna). Judge O'Malley[4] added that "[d]istrict courts across the country have struggled with our precedent in this area, concluding in large measure that, whatever their views of the merits of a particular preliminary injunction

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[4] As a district judge, Judge O'Malley had subscribed to a position similar to that of Judge Newman. *See Avery Dennison Corp. v. Alien Tech. Corp.*, 626 F. Supp. 2d 693, 699 (N.D. Ohio 2009); *Erico Int'l Corp. v. Doc's Mktg., Inc.*, Civ. No. 05–2924, 2007 WL 108450, at *9 (N.D. Ohio Jan. 9, 2007). His championing of the perplexed district judge is thus rooted in personal experience.

request, this court's precedent virtually mandates denial of all such motions." *Id.* at 1301 (O'Malley, J., dissenting).

Unpublished Federal Circuit opinions dating from after the *Kimberly-Clark* rehearing denial have cited *Titan Tire*. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 496 F. App'x 46, 50–51 (Fed. Cir. 2012) ("Regarding the likelihood of success on the merits, it was Roche's burden to show, in light of the burdens and presumptions that will inure at trial, that it will likely prove infringement and that it will likely withstand any invalidity challenge to the patent."); *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharm. Inc.*, 451 F. App'x 935, 938–39 (Fed. Cir. 2011) ("the trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings").[5]

Other post-*Titan* Federal Circuit panel decisions, however, both reported and unreported, seem to apply the legacy *Amazon* standard in reviewing preliminary injunction decisions. *See, e.g.*, *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013); *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1261 (Fed. Cir. 2012); *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, 431 F. App'x 884, 886–87 (Fed. Cir. 2011); *Altana Pharma*, 566 F.3d at 1005–06; *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1356 (Fed. Cir. 2008); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006). It is not clear, however, that the standard made any difference in those cases. In *LifeScan,* for example, the Court held that the defendant had "established a patent exhaustion defense as a matter of law." The other reported case applying the "substantial question" standard, *Sciele,* does not cite or discuss the relevance of *Titan.*

In this district, some recent decisions have followed the guidance of *Titan Tire*. *See, e.g.*, *Roxane Labs., Inc. v. Camber Pharm. Inc.*, Civ No. 14–4042, 2014 WL 3854140, at *2 (D.N.J. Aug. 6, 2014), *aff'd*, 596 F. App'x 922 (Fed. Cir.

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[5] Judge O'Malley wrote *Warner,* and Judges Newman and O'Malley sat on the unanimous panel in *Hoffman.*

2015) ("To obtain a preliminary injunction, Roxane must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent."). *See also e.g.*, *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 475, 497, 499 (D.N.J. 2015) (citing vulnerability standard, but also seemingly adopting the *Titan Tire* burden shifting analysis, concluding that "these Defendants ... have established a substantial question of invalidity ... and [the plaintiff] has not shown that this question of invalidity lacks substantial merit.").. Others, however, have cited the "vulnerability" language from *Amazon* without qualification. *See, e.g.*, *Yowie N. Am., Inc. v. Candy Treasure, LLC*, Civ No. 14–1409, 2014 WL 1871910, at *4 (D.N.J. May 8, 2014).

So what to do? Even if *Titan Tire* had, as a doctrinal matter, laid the issue to rest, there remains the problem of conflicting panel decisions. The Federal Circuit, like many, "has the rule that in the event of conflict between panels the earlier holding prevails until overturned en banc." *Sandoz*, 544 F.3d at 1371 (citing *Newell Companies v. Kenney Mfg. Corp.*, 864 F.2d 757, 765 (Fed. Cir. 1988)); *accord Texas Am. Oil Corp. v. U.S. Dep't of Energy*, 44 F.3d 1557, 1561 (Fed. Cir. 1995) ("This court applies the rule that earlier decisions prevail unless overruled by the court en banc, or by other controlling authority such as intervening statutory change or Supreme Court decision.") Thus *Titan Tire*, a panel decision, could not of its own authority overturn the standard announced in the earlier panel decision of *Amazon*. That rule, of course, is subject to the still more basic principles that intervening precedent of the U.S. Supreme Court must in all events control, and that Fed. R. Civ. P. 65 binds every district court, whether in a patent or non-patent case.

eBay is not so clearly on point as to simply overrule earlier Federal Circuit preliminary injunction cases, such as *Amazon*. If that were so, the issue would be an easy one. The *eBay* decision involved a remedial question: whether, after a trial in which infringement was found, the court should apply a general presumption that a permanent injunction should issue. The

preliminary injunction context poses problems of its own, involving the *probability* that infringement will be found, the allocation of risk in the interim, and the desirability of maintaining the *status quo.*

By the same token, however, *Titan Tire* does not merely overturn prior panel decisions, which, under the Court's operating procedures, it was not empowered to do. *Titan Tire* does not purport to overthrow, but rather to reconcile, the strands of the case law. I believe it succeeds in doing so—placing the burden on the defendant to raise a substantial issue, in which case the patentee must demonstrate the likelihood that it will succeed in meeting it ultimate burden of persuasion by clear and convincing evidence.

As a district judge, I am ill-equipped to enforce the internal operating procedures of the Federal Circuit,[6] or to decide which of its precedents to give priority. I tend to agree that the traditional preliminary injunction factors should be paramount, and that the Supreme Court has so signaled in *eBay.* Under that approach, where a substantial issue has been raised, the likelihood of success factor would require a court to weigh both sides' evidence and contentions, and to assess the plaintiff's likelihood of prevailing at trial. And that factor, of course, will be informed by the substance and procedures of patent law. I will therefore attempt to remain faithful to Federal Circuit case law and apply the *Titan* synthesis. As noted herein, however, I do not believe the standard would influence the result as to most issues, but I have noted where I believe it might.

2. Infringement

Fresenius argues that Fera's product, if marketed, will infringe independent claims 1 and 14 and dependent claims 2, 4, 15, and 16 of the '289 patent. (Prel. Inj. Br. § III.A.1) Fresenius's expert submits that Fera's proposed

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[6] I will not venture into the meta-question of how to reconcile a disagreement between panels as to whether there is a conflict between panel decisions.

generic formulations fall within the limitations of each of those claims. Fera's only challenge to those infringement allegation *per se* is that the patent requires a buffer. A buffer, argues Fera, should be defined as a liquid, whereas Fera's formulation is a lyophilized solid with no liquid components. (Prel. Inj. Opp. § II.A) In the accompanying claim construction opinion, I have construed the term "buffer" in a manner that is fatal to this argument. Consequently, I find that Fera has not raised a substantial issue, and that Fresenius is likely to succeed on this issue.

3. Patent validity

Fera next argues that Fresenius is unlikely to succeed on the merits because its patents are invalid. In support, Fera asserts the doctrines of double patenting; anticipation and the on-sale bar; obviousness; and inequitable conduct/unclean hands. I consider them in order.

i. Double patenting

The chief vice of double patenting is the potential for an unwarranted extension of the patent term. An inventor cannot, by re-patenting the same invention, extend the monopoly beyond the original term. Fera argues that the '289 patent is invalid because it is "virtually the same" as, or an obvious variant on, as the earlier-expiring '239 patent. (Prel. Inj. Opp. § 2.B)

The '289 patent was issued on April 14, 2015; the '238 and '239 patents were issued a few weeks later, on October 27, 2015. As it happens, however, the '289 patent received a patent term adjustment from the PTO under 35 U.S.C. § 154(b) that extended its anticipated expiration date to October 3, 2032.[7] Thus the '238 and '239 patents, though issued later, expire five weeks earlier, on August 29, 2032. These facts appear to be undisputed.

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[7] A section 154(b) extension is granted based on the USPTO's own delays in processing. 35 U.S.C. § 154(b).

In *Gilead Scis., Inc. v. Natco Pharma Ltd.*, the Federal Circuit held that an earlier *expiring* patent, even if *issued* later, would "qualify as an obviousness-type double patenting reference for a later-expiring patent." 753 F.3d 1208, 1217 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 1530 (2015). Albeit under circumstances different from this case, *Gilead* proclaimed categorically that the "patent expiration dates [] should control" because that approach best comports with the "bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Id.* at 1214–15. That holding receives further support from *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, which specifically mentioned patents that are "filed at the same time ... [yet] have different patent terms due to examination delays at the PTO." 764 F.3d 1366, 1373 (Fed. Cir. 2014) (citing 35 U.S.C. § 154(b)).[8]

Gilead reasoned that its holding would "preserve[] the ability of inventors to use a terminal disclaimer of later-expiring patents to create one expiration date." 753 F.3d at 1216. By a "terminal disclaimer," *Gilead* meant a patentee's voluntary relinquishment of the portion of the second-expiring patent's term that extends beyond that of the first-expiring patent. Such disclaimers, said *Gilead*, "effectively overcome any objection to improper term extension." *Id.*

Here, Fresenius notified the Court that it has filed for a terminal disclaimer that, if accepted by the PTO, would shorten the extended expiration of the '289 patent and bring it into conformity with those of the '238 and '239

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[8] *Gilead* confined the inquiry to the expiration date because the Uruguay Round Agreements Act ("URAA") "changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date." *Gilead*, 753 F.3d at 1211 (citing Pub.L. No. 103–465, § 532(a), 108 Stat. 4809, 4983–85 (1994)). Should there be a circumstance where a terminal disclaimer is unavailable, the holding that expiration dates control seems potentially draconian if it could invalidate a patent whose expiration date is later because of a patent term adjustment where the delay is solely the fault of the PTO.

patents. (*See* ECF. No. 291) In essence, Fresenius has agreed to give up the last five weeks of patent protection in August–October 2032. That concession, I find, removes any substantial basis for the double patenting objection. And because the extension resulted, not from any action of Fresenius but because of delay in the PTO's examination process, there is no inference of sharp practice.

While the PTO has not yet accepted the terminal disclaimer, it seems likely that they will do so, and Fera has not suggested otherwise. (*See* ECF No. 292) Thus, Fera is unable to raise a substantial question of invalidity on this issue, and Fresenius has demonstrated a likelihood of success on the merits as to double patenting.

ii. Anticipation and the on-sale bar

Fera argues that claims 1 and 2 of the '289 patent are anticipated by the grandfathered products and thus unpatentable under the on-sale bar. "To establish an on-sale bar, it must be shown that the device sold fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002) (internal quotation marks and citations omitted).

> A prior art reference can only anticipate a claim if it discloses all the claimed limitations arranged or combined in the same way as in the claim. However, a reference can anticipate a claim even if it d[oes] not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination.

Kennametal, Inc. v. Ingersoll Cutting Tool Co., 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation marks and citations omitted). In short, the grandfathered drug must literally duplicate the current formulation, or be so close as to be an obvious variant.

Specifically, Fera argues that the grandfathered levothyroxine formulations, which contain 500 µg of levothyroxine sodium per vial and either 10 or 15 mg of mannitol (Bedford; Nentwich 357), anticipate claims 1 and 2 of

the '289 patent, which describe 100 or 200 µg of levothyroxine and 2-4 or 3 mg of mannitol. ('289 Patent claims 1–2) Fera's argument is that a simple segregation of, say, 1/5 or 1/2 of the grandfathered product would produce a product indistinguishable from that described by the '289 patent. (Prel. Inj. Opp. § II.C.2)

The preparations of both Bedford's and Nentwich's grandfathered products belie this argument. Each describes a vial containing either 200 or 500 µg but with the amount of mannitol remaining at 10 or 15 mg, irrespective of the total amount of the lyophilized product. (Bedford; Nentwich 357) Thus, these formulations are consistent with Fresenius's claim that, prior to its discovery, the conventional wisdom was that more mannitol was better. (Prel. Inj. Br. 5)

> [U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Nor is it apparent from these grandfathered formulations that a person of ordinary skill in the art would realize that stability would be enhanced by a reduction in the amount of mannitol when creating a lower dosage version.

The grandfathered formulations may contain the same or similar ingredients, but they keep the mannitol proportion consistent for different sized formulations. They therefore do not arrange the proportions of the ingredients in a way that is identical to, or an obvious variant on, the formulation in the '289 patent. Under the "substantial issue" standard, this is a closer question. Nevertheless, in light of the considerations discussed here and in the following subsection, Fresenius has demonstrated a likelihood of success.

iii. Obviousness/on sale bar

Relatedly, Fera argues that portioning the grandfathered formulations can demonstrate the obviousness of the '289 patent. They claim that Fresenius's formulation with less mannitol would be an obvious variant of the

grandfathered Bedford or Nentwich formulation when creating a 100 µg composition (Prel. Inj. Opp. § II.C.3) To simplify, Fresenius's patent teaches that the amount of mannitol, contrary to expectation, should remain at between 2 and 4 µg, irrespective of the sized of the dose. But look, says Fera. Take Nentwich's 500 µg formulation, which contains 15 µg of mannitol, and divide it by five. The result is a 100 µg formulation, which contains 3 µg of mannitol, a formulation that falls within the scope of the '289 patent. This, however, misses the point of the claimed innovation.[9] The innovation, says Fresenius, is that a composition of any size can be stabilized by keeping the level of mannitol low—*i.e.*, by *not* multiplying or dividing the amount of mannitol to keep it in a fixed proportion to the amount of the formulation as a whole. Fera presents no substantial argument as to why a person of ordinary skill in the art would act otherwise and challenge what Fresenius presents as the conventional wisdom: the larger the dose, the larger the amount of mannitol.

"If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 127 S. Ct. 1727 (2007). Fera does not successfully suggest that the '289 patent is a predictable variation, nor has Fera argued why, prior to the discovery upon which the patent rests, a person of ordinary skill in the art would see the benefit of reducing the amount of mannitol.

Further, even if the obviousness showing had been stronger, Fera does not bring evidence to dispute the unexpected properties allegedly discovered by Fresenius. "Objective evidence of nonobviousness can include ... unexpected properties of the claimed invention. These objective considerations can protect

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[9] Fresenius points out that the Nentwich formulations were not shown to contain a phosphate buffer or phosphate salt, either. That circumstance renders their status as prior art even more problematic.

against the prejudice of hindsight bias, which often overlooks that the genius of invention is often a combination of known elements which in hindsight seems preordained. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013).

I observe in passing that the grandfathered formulation remains unpatented. At oral argument counsel pointed out, without contradiction, that anyone (subject to regulatory approvals, of course) is free to market the grandfathered formulation. The Fresenius formulation, now patented and being marketed, is an incremental improvement on that formulation, which has a longer shelf life. Clearly this is not a scientific breakthrough, but the record is uncontradicted that it is a previously-unanticipated improvement. Fera's "slice and dice" argument does not raise a substantial question as to the legitimacy of the innovation. Fresenius is likely to prevail on this issue.

iv. Inequitable conduct

Fera also asserts the doctrine of inequitable conduct. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). The inequitable conduct claim here is that Fresenius "concealed but-for material information showing that the prior art lyophilized compositions were as stable as the purported invention." Prel. Inj. Opp at 1.

Many of Fera's inequitable conduct claims, asserted as counterclaims, are the subject of a motion to dismiss.[10] In their preliminary injunction briefs, the parties incorporate by reference their briefs from that motion to dismiss.

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[10] Some of the arguments are new and have not been pleaded. (Prel. Inj. Opp 24–25; Prel. Inj. Reply 10)

(Prel. Inj. Opp. 22; Prel. Inj. Reply 10 n.4) The discussion here is therefore relevant to both the motion to dismiss and the preliminary injunction motion.

In *Therasense, Inc. v. Becton, Dickinson & Co.*, the Federal Circuit, sitting en banc, set out the contours of the inequitable conduct doctrine:

> To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference. In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

649 F.3d 1276, 1290 (Fed. Cir. 2011) (internal quotation marks and citations omitted). Intent and materiality are the elements of an inequitable conduct claim and independent evidence of each is required to prove the defense. *Id.* ("A court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.").

Therasense also set forth the test for proving the intent element:

> Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. Indeed, the evidence must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances. Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.

Id. at 1290–91.

Therasense also refined the Federal Circuit's standard for materiality:

> This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been

> aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.

Id. 1291–92.

I briefly address and deny the motion to dismiss, which is analyzed on a lower standard than, and is logically prior to, the preliminary injunction.

The parties dispute whether the "single most reasonable inference" test of intent applies on a motion to dismiss. Prior to *Therasense*, the Federal Circuit set out in *Exergen Corp. v. Wal-Mart Stores, Inc.* the requisites for pleading inequitable conduct:

> [T]o plead the "circumstances" of inequitable conduct with the requisite "particularity" under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

575 F.3d 1312, 1328–29 (Fed. Cir. 2009). "*Exergen* involved a motion to amend after a full trial on the merits." *Jersey Asparagus Farms, Inc. v. Rutgers Univ.*, 803 F. Supp. 2d 295, 308 (D.N.J. 2011). But, "courts in this District have held that *Exergen* applies to the pleading stage." *Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, No. CIV.A. 11-4380 JBS, 2013 WL 3216145, at *5 (D.N.J. June 24, 2013) (collecting cases). Further, the Federal Circuit itself continued to cite *Exergen* in a motion to dismiss case decided after *Therasense*:

> A charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff's complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO. *Exergen v. Wal–Mart Stores, Inc.*, 575 F.3d

1312, 1318, 1330 (Fed. Cir. 2009); *see generally Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

Delano Farms Co. v. California Table Grape Comm'n, 655 F.3d 1337, 1350 (Fed. Cir. 2011).

In essence, Fera pleads that various persons associated with Fresenius's patent prosecution knew that the grandfathered formulations performed well in stability testing. The very heart of the patent, however, was its claim of improved stability. These actors therefore allegedly compared the stability of their formulation, not to the grandfathered product, but to the poor stability tests of formulations other than the one Fresenius had previously marketed. They referred to these different formulations as "prior art" or "conventional," allegedly with the intent to mislead the patent examiner.

That, in my view, meets the relatively low threshold of being a sufficient allegation. The motion to dismiss is therefore denied. I move on to the preliminary injunction aspect.

The *Therasense* standard applies to the likelihood of success inquiry on a preliminary injunction. At the preliminary injunction phase, however, the Court is predicting the future; it is required "to assess the potential of a 'clear and convincing' showing in the future, but in terms of what is 'more likely than not' presently." *Titan Tire*, 566 F.3d at 1380. And of course, unlike a motion to dismiss, a preliminary injunction application requires examination of the affidavits and proofs put forward by the parties.

The '289 patent claims priority over a provisional application, U.S. Provisional Patent Application No. 61/529,084 ("'084 application").[11] (Fera Answer ¶ 41) The '289 patent actually issued from non-provisional Patent Application No. 13/597,884 ("the '884 application"). (Fera Answer 42) The three

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[11] The inequitable conduct allegations are essentially the same for the other two patents. I will focus on the '289 patent because it is the subject of the preliminary injunction but the motion to dismiss ruling applies with equal force to all three patents.

inventors listed on the '084 application are the same as those on the '289 Patent: Zhi–Qiang Jiang, Arunya Usayapant, and George Monen. (*See* '084 application cover sheet; '289 Patent)

Page 6 of the '084 application contains two tables. The first table contains the ingredients of five levothyroxine formulations, labeled A–E, that underwent stability testing. All have 10mg of mannitol and between 100 and 500 µg of levothyroxine. Formulations A and B, labeled as "conventional," contain tribasic sodium phosphate. Formulations C, D, and E, labeled as "modified," contain dibasic sodium phosphate. The A/B "conventional formulations," according to Fera, contain essentially the same formulation as the grandfathered Bedford formulation. (Fera Answer ¶¶ 47–50, 74–76) Formulations C,D, and E contain dibasic sodium phosphate, and are similar to the formulation that is the subject of the '289 patent.

Table 2 lists amounts of liothyronine (or "T3"), a degradation product of levothyroxine, in formulations C-E tested at different times over 18 months. ('084 application at 6) "Each of formulations C, D and E included 0.17 - 0.18% T3 at the beginning of the testing. The amount of T3 increased over time in formulations C and D, whereas the amount of T3 in formulation E remained relatively stable." ('084 application at 7 ¶ 0026) The results as to "conventional" formulations A and B are not presented in a table, but the '084 application explains in text:

> The instability of levothyroxine in the modified formulations C and D was unexpected in view of the behavior of the conventional formulations A and B. During storage at 25° C for a period of from 4 to 19 months, the amount of T3 in formulation A varied from 0.16 - 0.34%, but did not exhibit an increase over time. Likewise, the amount of T3 in formulation B varied from 0.22 - 0.27% during storage at 25 °C for a period of from 8 to 28 months, but did not exhibit an increase over time.

('084 application at 7 ¶ 0028) It further explained that "[s]urprisingly, the stability of levothyroxine in lyophilized formulations containing dibasic sodium phosphate *instead of tribasic sodium phosphate* was found to decrease with an increase in the ratio of mannitol to levothyroxine in the formulation." ('084

application at 7 ¶ 0031 (emphasis added; *see also* Fera Answer ¶ 59) In other words, the stabilizing effect that is the foundation of the claimed invention is observed in relation to the dibasic, but not the tribasic, formulation.

Here is the problem, says Fera: The non-provisional '884 application does *not* compare formulations with dibasic sodium phosphate to those with tribasic. (Fera Answer ¶ 65) That '884 application was the subject of four separate office actions. In the fourth rejection the examiner notes that the data presented by the applicant is not a direct comparison with the relevant prior art, and that art teaches a formulation containing tribasic sodium phosphate. (Fera Answer ¶ 120)[12] Fera faults the applicants for allegedly never submitting to the patent examiner the original stability test results on formulations A and B, which are tribasic sodium formulations. (*See, e.g.*, Fera Answer ¶ 124)

A declaration by Dr. Usayapant was submitted on December 23, 2014, as part of a response to the fourth rejection. (Usapayant Decl.) In that declaration Dr. Usapayant refers to the stability benefits of the new formulation as compared to conventional formulations. She cites to a table comparing formulations, all containing dibasic sodium phosphate, but containing varying amounts of mannitol. (Usayapant Decl. ¶ 9; *see* Fera Answer ¶ 128) Usayapant's declaration elsewhere refers to "prior art," but Fera complains that these references do not explicitly distinguish between prior art formulation as containing dibasic or tribasic sodium phosphate. (Usayapant Decl. ¶ 14–17; *see* Fera Answer ¶ 132–33) Usayapant's data, however, and her stability comparisons, clearly relate to dibasic.

The examiner, who was aware of the dibasic/tribasic issue, found the arguments filed on December 23, 2014, persuasive and issued a notice of allowance. (Fera Answer ¶ 149; Notice of Allowance 2). She highlighted that

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[12] Fera stresses the number of times that Fresenius's applicants represented that their formulation was an improvement over conventional formulations. If this was an attempt to fool the patent examiner, as Fera claims, she clearly was not falling for it, as witnessed by the four rejections. (Fera Answer ¶¶ 73–118)

"since Applicants have discovered that the previous formulations are unstable, and that decreasing the amount of mannitol to between 2 and 4 mg increases stability, leading to a more stable product having an increased shelf-life, the claims of the instant application are novel and nonobvious over the closest related prior art." (Notice of Allowance 6)

I see no substantial evidence of misrepresentation, or intentional withholding of material information from the patent examiner. The analysis is hampered somewhat by Fera's failure to depose the persons involved in the patent prosecution. The necessary intent to deceive, *see Delano Farms Co., supra,* for example, will often depends on such evidence. There is enough here, however, to demonstrate the point. The patent examiner knew very well that some of the prior art taught a tribasic formulation. The provisional application, containing the allegedly omitted information, was before the patent examiner, who should be presumed to have been familiar with it. More fundamentally, throughout the process, the relevant apples-to-apples comparison, as presented to and understood by the examiner, was between dibasic formulations containing different proportions of mannitol. That was the thrust and point of the application.

This is one area where the preliminary injunction standard could make a difference. My finding that Fera has not raised a substantial question is based primarily on the state of the paper record, but the question is a close one. Under the traditional Rule 65 standard, I find with more ease that Fresenius has shown a likelihood of success on patent validity in relation to the inequitable conduct issue.

v. Unclean hands

Fera asserts the equitable doctrine of unclean hands. In the present context, however, this seems to be another name for its other contentions. Thus, Fresenius is alleged to have unclean hands because it engaged in double patenting or violated its duty of candor to the USPTO regarding prior art. I have discussed those contentions more specifically above; they have no more likelihood of success under the rubric of unclean hands.

Fera adds that Fresenius has unclean hands because it did not report Fera's own inequitable conduct allegations to the PTO. I do not give significant weight to this bootstrapping allegation.

B. Irreparable Harm

Patent law recognizes the necessity of injunctive relief "to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money." *Hybritech, Inc. v. Abbott Labs.*, 849 F. 2d 1446, 1457 (Fed. Cir. 1988).

"[P]rice erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 926 (Fed. Cir. 2012). Loss of market share, for example, "constitutes irreparable injury because market share is so difficult to recover." *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1991), *aff'd*, 945 F.2d 416 (Fed. Cir. 1991). Price erosion, because of the difficulty of reversal, may constitute irreparable harm. *Canon, Inc. v. GCC Intl Ltd.*, 263 F. App'x 57, 62 (Fed. Cir. 2008). The right to exclude direct competition in a limited sphere, a right inherent in the grant of a patent, is irreparably harmed by the loss of sales and the competitive foothold that the infringer will gain. *See Systemation, Inc. v. Engel Indus., Inc.*, 194 F.3d 1331, 1999 WL 129640 at *6 (Fed. Cir. 1999).

In addition to harm as such, the patentee must show that there is a "sufficiently strong causal nexus" between the infringement and the harm. *Apple Inc. v. Samsung Electronics Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). In particular, there must be a connection between the lost sales or market share, and the "infringing feature" of the competing product. *Id.* at 1374 ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.").

Fera indisputably seeks to be Fresenius's direct competitor. Through its ANDA, it seeks to market precisely the formulation as to which Fresenius obtained FDA approval and patent protection. *See Systemation, Inc.*

(emphasizing loss of sales to "direct competitor" as emblematic of irreparable harm).

In Fera's view, the presence of the grandfathered product places a natural ceiling on the value of the patented product, which has a longer shelf life but the same efficacy. Still, the evidence shows a dramatic increase in the price of the patented product—in the five- to six- fold range—for which there is no plausible explanation except for its patented status. The inference is inescapable that customers are paying a premium for its stability. Fera itself could presumably market the grandfathered product, but has not chosen to do so, instead piggy-backing on the FDA-approved Fresenius product, which now enjoys some $80 million in annual sales. That in itself is suggestive of the value of the innovation, although I do not discount an element of market irrationality, lag, or less-than-perfect market information.

Because the product is one administered in hospitals, the customer base comprises a relatively small class of Group Purchasing Organizations (GPOs). (Meacham ¶ 10) Those customer relations, the reputation of Fresenius, and the purchasers' experience with the product, are therefore of primary importance. The market clout of such GPOs also implies that, should the price erode as a result of infringement, a price rebound may meet stiff resistance.

Historical sales of the grandfathered product do give us an informational backdrop. That market, however, has apparently dried up. The market for the patented product is not mature, or even well established. Thus the effect of Fera's projected price cutting on Fresenius's (currently 100%) market share is difficult to predict or quantify. And market share, once lost, is difficult to regain in the event of a mistaken denial of injunctive relief. *See Henkel Corp.*, 754 F. Supp. at 1322.

Fera cites the presence of a new competitor in the market: Par Sterile Products, LLC, and affiliates ("Par"). Par, the parties seem to agree, is not precisely a third-party entrant. Rather, Par has entered into licensing and distribution agreements with Fresenius on March 18, 2016, and July 1, 2016. As a licensee, Par is within the patent estate, *i.e.*, under the umbrella of

Fresenius's patent protection. "[T]hat a patentee has license others under its patents does not mean that unlicensed infringement must also be permitted while the patents are litigated." *See Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) (citing *eBay*, 547 at 393); *Abbott Labs. V. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008)). A license, an ordinary means of patent exploitation, does not imply that infringement by a non-licensee is harmless. At best, it is a weak indicator that damages might be quantified as a reasonable royalty, but even that is but one factor among many.

The irreparable harm factor tips in favor of Fresenius.

C. Balance of Harms

On the balance of harms, Fera essentially argues that Fresenius has made large profits and can well afford competition from Fera. Because some version of the product has long been in existence, research and development costs, as well as regulatory approval, allegedly set Fresenius back only $3 million. The product, which has accounted for some $310 million in sales over the years, supposedly accounts for only 5% of Fresenius's revenue.

Fera's argument amounts to a contention that, even if it turns out to have been infringing, Fresenius can well afford the competitive loss. Fresenius, however, has made a showing of likelihood of success on the issues of validity/infringement. The implication is that Fera has not made a strong showing that it has a right to go to market; it is not likely to suffer a legally cognizable "loss" by being enjoined. I therefore cannot find that the balance of harms favors Fera.

D. Public Interest

Cheaper generic drugs, as Fera points out, are in the public interest. That argument, of course, proves too much; the patent laws reflect a balance between that public policy and the policy of encouraging innovation through the grant of a limited patent monopoly. Where the patent holder is acting within the lawful scope of its patent, public policy favors an injunction. *See*

generally PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1567 (Fed. Cir. 1996).

III. CONCLUSION

The motion to dismiss inequitable counterclaims is denied, but the motion for a preliminary injunction is granted. An appropriate order accompanies this Opinion.

Dated: September 20, 2016

Hon. Kevin McNulty
United States District Judge